B51 Poking Holes in the Suspect's Story: An Overview of Pharmaceutical Theft and Tampering Analysis

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The goal of this presentation is to present the forensic community with an overview of the analytical approaches used by the FDA's Forensic Chemistry Center (FCC) in casework involving the theft of contents from and/or tampering with pharmaceutical vials and syringes.

This presentation will impact the forensic community and/or humanity by presenting examples as an analytical roadmap for those in the general forensic chemistry community who may lack experience analyzing similar pharmaceutical fraud/tampering cases.

This poster will highlight the approaches used by the FCC in cases involving pharmaceutical theft and/or tampering. The FCC receives suspect narcotic vial and syringe evidence from all over the U.S., and is often asked to answer three basic questions: Has the integrity of the product container been compromised? How much, if any, of the original product remains? What, if anything, was used as a replacement medium (adulterant)?

The type of pharmaceutical theft most commonly encountered occurs in hospitals and nursing homes where an individual removes a portion of a narcotic solution from a vial or syringe. In most cases, the individual will "replace" the contents removed with some sort of diluent, such as saline or bacteriostatic water. The FCC has also received cases where the original narcotic product was replaced with another, less potent narcotic. The motive for using a less potent narcotic may be to minimize the chances of the theft being discovered, as a patient receiving the less potent narcotic would be less likely to complain about the pain medication not working.

When a suspect syringe or vial arrives at the FCC, its first stop is in the Microscopy Lab. There the vials and syringes are examined for evidence of tampering and determination of what may have been used to access and remove the contents of vials and syringes. Using both Polarized and Stereoscopic Light Microscopy (PLM/SLM), the microscopists are frequently able to determine the number of times, for instance, a vial's rubber septum has been punctured. Excessive numbers of punctures can be indicative of product theft, adulteration, replacement, or other types of fraud. The shape and characteristics of the puncture hole(s) provides evidence as to what sort of tool was used to puncture the septum.

The next step in the process is GC-MS analysis. The contents of the suspect vials and syringes are screened for the presence of the active ingredients, as well as any additional drugs or unusual components. If the contents appear to be diluted, this analysis may indicate what was used as a diluent. For example, if benzyl alcohol (a preservative) is detected in the suspect item using the GC-MS screen, but not the controls, bacteriostatic water or saline may have been used for replacement.

After determining the composition of the vial/syringe contents, the compounds present are quantified (if possible) by HPLC with UV detection in order to determine the extent of dilution.

The final step, if necessary, in the analysis of these samples is elemental analysis. If during the GC-MS analysis it is determined that the contents were diluted, ICP-AES analysis can be performed to evaluate the contents for the presence of excess sodium relative to untampered control pharmaceutical samples. The amount of excess sodium relative to the dilution of the active pharmaceutical ingredient may be consistent with the replacement of the stolen contents with saline.

Once all of the necessary analyses are completed, the pieces of the puzzle start to fit together. Generally, the FCC can report back to the case agent with the following information: how many times the suspect product was accessed, what type of tool was used to access the contents, whether there is active ingredient remaining, whether another drug (or a potentially harmful substance) was used in replacement, how much of each identified component is present in the solution, and whether saline was used as the diluent.

Pharmaceuticals, Tampering, Theft

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